Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014

Message Text

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PAGE 01 STATE 164591
ORIGIN HEW-06

INFO OCT-01 EUR-12 EA-12 ISO-00 OES-07 COME-00 MED-03
/041 R

DRAFTED BY DHEW/FDA: JRW:INROTH, MD:VO
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/CE:SKLINGAMAN(INFO)
EUR/EE:JGLENN(INFO)
EUR/NE:CSCHALLER(INFO)
EA/ANP:WGALLAGHER(INFO)
EUR/CE:JHURLEY,JR(INFO)
----------075122 282210Z /14
P 282013Z JUN 78
FM SECSTATE WASHDC
TO AMEMBASSY BONN PRIORITY
AMEMBASSY PRAGUE PRIORITY
AMEMBASSY HELSINKI PRIORITY
AMEMBASSY BERN PRIORITY
AMEMBASSY COPENHAGEN PRIORITY
AMEMBASSY WELLINGTON PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, GW, CZ, FI, DA, NZ, SZ, UK,
AS, LE, CO, HU, NL, JM, MX

SUBJECT: FDA ADVISORY - FIRM INITIATED RECALL OF CERTAIN
IMPROPERLY FITTING DISPOSABLE DIAPHRAGM DOMES (RECALL T
115/116-8)

1. FDA ADVISES OF THE FOLLOWING FIRM INITIATED RECALL:
PRODUCT INVOLVED - THE PRODUCTS INVOLVED ARE GOULD STATHAM
DIAPHRAGM DOMES, MODELS TA1007D (T-115-8) AND TA1009D
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(T116-8). PRIMARILY FOR BLOOD PRESSURE MEASUREMENT.

2. PRODUCT IDENTIFICATION - MODEL TA1007D IS A CELLOPHANE
AND PAPER PACKAGE WITH LABELING READING IN PART AS FOLLOWS:
"STERILE NON-PYROGENIC LINDEN FITTING GOULD STATHAM
DISPOSABLE DIAPHRAGM DOME, MODEL -23DB P23DC P23DD P23DE
P23V P23 1A - DO NOT REUSE DIAPHRAGM DOMES - GOULD, INC.,

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STATHAM INSTRUMENTS DIVISION 2230 STATHAM BLVD., OXNARD, CALIFORNIA 9,030.

MODEL TA1009D IS ALSO IN A CELLPHANE AND PAPER PACKAGE AND IS LABELED IN PART AS FOLLOWS: "STERILE NON-PYROGENIC LUER LOK FITTINGS GOULD STATHAM DISPOSABLE DIAPHRAGM DOME, MODEL TA1009D FOR USE WITH GOULD STATHAM TRANSDUCER MODELS; P23DB, P23DC, P23DE, P23V 1A. ALL LOT NUMBERS OF BOTH MODELS ARE INVOLVED.

3. MANUFACTURER/RECALLING FIRM: THE MANUFACTURER AND RECALLING FIRM IS GOULD INC., MEASURING SYSTEMS DIVISION, 2230 STATHAM BLVD., OXNARD, CALIFORNIA 93030.

4. REASON FOR RECALL: THE DOMES MAY NOT FIT PROPERLY ON GOULD TRANSDUCERS MODELS -23DB, P23DC, P23DD, P23DE, AND P23V DUE TO SURFACE IRREGULARITIES IN THE TRANSDUCER WHICH MAY CAUSE LEAKAGE AND A SMALL BUT POSSIBLE CLINICALLY SIGNIFICANT DIFFERENCE IN PRESSURE READINGS.

5. THE PROBLEM WAS FIRST DISCOVERED AND REPORTED TO THE FIRM BY THE VETERANS ADMINISTRAIION, DES MOINES, IOWA THOUGH NO INJURIES WERE INVOLVED. THIS OCCURED IN NOVEMBER FOLLOWED BY GOULD REPEATING AND VERIFYING THE VA'S TESTS AND THEY TEHN BEGAN THE RECALL ON 4-18-78 BY LETTER. BEGINNING 4-18-78 THE FIRM SENT LETTERS TO FIELD SALESMEN, UNCLASSIFIED

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DISTRIBUTORS, AND USERS OF THE PRODUCTS ADVISING THEM OF THE PROBLEM AND GIVING THEM NEW INSTRUCTIONS FOR THE USE OF THE DISPOSABLE DOMES VINYL DISC, MODEL TA7004, USED WHEN MOUNTING THE DOMES ON P23DB, C, D, OR E TRANSDUCERS. THE FIRM RECOMMENDED IN THEIR LETTER THAT THE DISPOSABLE DOMES NOT BE USED ON MODEL P23V TRANSDUCERS.

6. POSTS ARE REQUESTED TO CONTACT FOREIGN ACCOUNTS AS PROVIDED BY FIRM TO FDA TO DETERMINE IF THEY HAVE RECEIVED INFORMATION LETTER REGARDING PROBLEM AND ITS SOLUTION. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING ADVISORY SHOULD BE DIRECTED TO GOULD ATTENTION DR. ARCHER S. GORDON, MD.D., MEDICAL DIRECTOR.

7. FOREIGN ACCOUNTS AS PROVIDED TO FDA BY FIRM ARE:

MR. F. WALLNER, BMT MESSTECHNIK, 22 HUMBOLTSTRASSE, 1000 BERLIN 33, GERMANY

DEPARTMENT OF PHARMACOLOGY, MEDICAL FAC. OF PALACKY UNIVERSITY, 775 15 OLOMOUC, HNEVOTISKA NO.3, CZECHOSLAVAKIA

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DACHSER SPEDITION, FRANKFURT AIRPORT, FRANKFURT, GERMANY

EUT YO, HELSINKI 10, FINLAND

SIMON AND WEELS EF AND F A/S, ROSKIDEVEJ 14 DK 2620,
ALBERTSLUNO, DENMARK

FLETCHER HEALTH AND SCIENCE, GREAT S. RD. PENROSE PRIVATE
RD., AUCKLAND, NEW ZEALAND

WILLSCHLEGER AND CO., P.O.BOX CH-400N2-4 UNTEREIZ HUEBERG,
BASEL, SWITZERLAND

P.K. MORGAN, 10 MANOR RD., CHATHAM KENT, ENGLAND
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MEDOE COMPANY PTY. LTD., P.O.BOX 442, SOUTH MELBOURNE 3205,
AUSTRALIA

MEDOS COUNTY, P.O.BOX 422 S. MELBOURNE SEC. 5, AUSTRALIA

A NASRAITOH, MD.D, AMERICAN UNIVERSITY HOSPITAL, BEIRUT,
LEBANON

PORFIRIO E. PEREZ, M.D., UNIVERSIDAD NARIOVO DE COLOMBIA,
CALLE 84 NO. 7-30 APT. 301, BOGOTA, COLOMBIA

NIELS KROMOND B. SC, DESA ELEKTRONEK A/S, DK 2740 SKOVLUNDE
DENMARK

DR. GUILLO MUNSON, UNIVERISTY OF PERCEZIA, INSTITUTO DI
SEMIOTICA, MEDICO, ITALY

INSTITUTE OF EXPERIMENTAL SURGERY, UNIVERSITY MEDICAL
SCHOOL, P.O. BOX 464, SZEGED, HUNGARY

L.M. VAN GELDER, CATHERINZAIEKEHUIS, MICHEL ANGELOLAAN 2,
EINDHOVER, HOLLAND

MEDICAL ELECTRONICS AND SUPPLIES LTD., ELECTRONICS FOR
MEDICINE INC., 7A NORTHSIDE DR., KINGSTON 6, JAMAICA,
WEST INDIES

DR. SANDOR NAGY, UNIVERISTY OF SZEGAD, 6701 SZEGAD, P.O.
BOX 464, HUNGARY

MISS M.E. LEESON, FISONS LTD, BAKEWELL RD., LOUGHBOROUGH,
LEICS, ENGLAND LE110NF
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GILBERTO MONTIER MD.D, SAN JOSE HOSPITAL, MONTERREY,
N.L., MEXICO VANCE

NNN

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
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Current Classification: UNCLASSIFIED
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Control Number: n/a
Copy: SINGLE
Draft Date: 28 jun 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE164591
Document Source: CORE
Document Unique ID: 00
Drafter: JRW:INROTH, MD:VO
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780268-0268
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780610/aaaaaivh.tel
Line Count: 178
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 010f077c-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
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Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
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Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2134359
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - FIRM INITIATED RECALL OF CERTAIN IMPROPERLY FITTING DISPOSABLE DIAPHRAGM DOMES (RECALL T 115/116-8)
TAGS: OGEN, ETRD, EIND, TBIO, GE, CZ, FI, DA, NZ, SZ, UK
To: BONN PRAGUE MULTIPLE
Type: TE
vdkvgwkey: odbc://SAS/SAS.dbo.SAS_Docs/010f077c-c288-dd11-92da-001cc4696bcc
Review Markings:
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